



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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PURGED *RJK*

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

September 17, 1999

xc: HFI-35
DWA

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 99 - 49

Mary Bakken
Regional Director – Fairview Clinics
Fairview Health Systems
2312 So. Sixth Street
Minneapolis, Minnesota 55420

Dear Ms. Bakken:

On August 20, 1999, a representative of the State of Minnesota, acting on behalf of the Food and Drug Administration (FDA), inspected your Fairview Oxboro Clinic facility at 600 West 98th Street, Bloomington, MN 55420. This inspection (ID = 1294940007) revealed a serious regulatory problem involving the mammography at your facility.

Under a United States Federal law, the Mammography Quality Standards Act of 1992 (MQSA), your facility must meet specific requirements for mammography. These requirements help protect the health of women by assuring that a facility can perform quality mammography. Based on the documentation your site presented at the time of the inspection, the following Level 1 and Level 2 findings were documented at your facility:

Level 1 Non-Compliance:

Phantom QC records were missing for 12 weeks for the mammography unit
(~~~~~).

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Level 2 Non-Compliances:

There was no written procedure for handling mammography consumer complaints at the Fairview Oxboro Clinic.

Interpreting physician (~~~~~), did not meet the continuing experience requirement of having read or interpreted 960 patient examinations in a 24-month period.

The specific problems noted above appeared on your MQSA Facility Inspection Report, which was issued to your facility following the close of the inspection.

Note: Individuals failing to meet either the "Initial" and/or "Continuing" MQSA requirements must immediately cease performing mammography independently. For physicians the "Continuing" requirements include either the lack of appropriate CME/24 months, or Number of Interpretations/36 months. Requirements for re-qualification are listed in the Final Regulation that became effective on April 28, 1999.

FDA acknowledges that both Level 2 Non-Compliances have been resolved. The compliant procedure was supplied via a fax dated September 7, 1999. A September 8, 1999, letter from ~~~~~ has indicated that ~~~~~ has re-qualified by reading under Direct Supervision.

Because these conditions may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility, they represent a serious violation of the law which may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, placing your facility under a Directed Plan of Correction, charging your facility for the cost of on-site monitoring, assessing civil money penalties up to \$10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards, suspension or revocation of your facility's FDA certificate, or obtaining a court injunction against further mammography.

It is necessary for you to act on this matter immediately. Please explain to this office in writing within 15 working days from the date you received this letter:

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- the specific steps you have taken to correct all of the violations noted in this letter;
- each step your facility is taking to prevent the recurrence of similar violations;
- sample records that demonstrate proper record keeping procedures if the findings relate to quality control or other records.

Please submit your response to Thomas W. Garvin, Radiological Health Specialist, Food and Drug Administration, 2675 No. Mayfair Road, Suite 200, Milwaukee, WI 53226-1305.

Finally, you should understand that there are many FDA requirements pertaining to mammography. This letter pertains only to findings of your inspection and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for mammography facilities by contacting the Mammography Quality Assurance Program, Food and Drug Administration, P.O. Box 6057, Columbia, MD 21045-6057 (1-800-838-7715) or through the Internet at <http://www.fda.gov/cdrh/mammography/index.html>.

If you have specific questions about mammography facility requirements or about the content of this letter please feel free to phone Mr. Garvin at (414) 771-7167 x 12.

Sincerely,



Edwin S. Dee
Acting Director
Minneapolis District

TWG/ccl